NOV 1 5 2001

K013526

CAPIOX® RX Hardshell Reservoir

Submitter Information:
This premarket notification is submitted by:

Garry A. Courtney
Terumo Cardiovascular Systems
Regulatory Affairs Specialist
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Date of Preparation: October 12, 2001

Device Names:

Proprietary Name:	CAPIOX® RX Hardshell Reservoir
Common Name:	Blood Reservoir
Classification:	CPB Reservoirs are classified as Class II devices.

Predicate Device:
The CAPIOX® RX Hardshell Reservoir is substantially equivalent in intended use, materials, design, technology and principles of operation, and performance to the CAPIOX® SX Hardshell Reservoir (K002238).

Intended Use:
The CAPIOX® RX Hardshell Reservoir is a hardshell reservoir used to store blood during extracorporeal circulation from both the venous line and the cardiotomy line. The reservoir contains filters to remove particulate matter and defoamers to facilitate air bubble removal.

The Hardshell Reservoir is also used for post-operative chest drainage and autotransfusion procedures to aseptically return blood to the patient for blood volume replacement.

The Hardshell Reservoir is also used with the vacuum-assisted venous return technique during cardiopulmonary bypass.

The Hardshell Reservoir contains X-Coating, which is intended to reduce platelet adhesion on the surfaces of the device.

The device may be used for procedures lasting up to 6 hours.

Principles of Operation and Technology:
The CAPIOX® RX Hardshell Reservoir is used as a blood storage device during and after cardiopulmonary bypass procedures. Venous blood enters the reservoir via gravity, or by way of external vacuum that may be applied to the reservoir.

Venous blood that is drawn from the patient enters the device through the venous blood inlet port. The blood passes through a defoamer to remove air from the blood and through a filter for removal of particulates.

Blood may also be suctioned into the reservoir from the cardiotomy field. This blood enters the device through the cardiotomy blood suction ports. As with the venous blood, the blood passes through a defoamer to remove air and through a filter for removal of particulates.

Blood exits the device via gravity through the blood outlet port and is pumped through the remaining cardiopulmonary bypass circuit.

Design and Materials:
The *design* of the CAPIOX® RX Reservoir consist of a hard casing reservoir. It has a rotatable venous blood inlet port that permits minimizing tubing lengths, which could result in lower circuit priming volumes. The total capacity of the reservoir is 4000 mL.

The CAPIOX® RX Hardshell Reservoir contains a defoamer and a screen filter in the venous blood inlet section. The defoamer resides in the upper part of the reservoir, thus permitting blood to reside in the lower section of the reservoir.

The cardiotomy section of the RX reservoir contains a defoamer and a filter to facilitate air removal and the removal of particulates from suctioned blood entering the reservoir.

The generic *materials* used in the CAPIOX® RX Hardshell Reservoir are polycarbonate, polypropylene, PET, polyvinyl chloride, polyurethane, nylon, stainless steel and ceramic. The device also contains Terumo's X-Coating polymer solution.

Performance Evaluations:
The performance of the CAPIOX® RX Hardshell Reservoir is substantially equivalent to the performance of the predicate devices. The following tests were conducted to demonstrate equivalence in performance:

- Filter Defoaming – Venous Section
- Filter Defoaming – Cardiotomy Section
- Pressure Drop/Flow Rate Testing – Venous Section
- Pressure Drop – Cardiotomy Section
- Filtration Efficiency – Cardiotomy Section
- Effects Upon Cellular Blood Components
- Pressure Integrity Testing
- Tubing Connection Strength

Substantial Equivalence Comparison:
The CAPIOX® RX Hardshell Reservoir is substantially equivalent to the predicate SX Hardshell Reservoir device as follows:

Intended Use: The RX Reservoir and the predicate SX Reservoirs share the same intended uses. Each is used to store blood during extracorporeal circulation from both the venous line and the cardiotomy line. The reservoirs contain filters to remove particulate matter and defoamers to facilitate air bubble removal.

The Hardshell Reservoirs are also used for post-operative chest drainage and autotransfusion procedures to aseptically return blood to the patient for blood volume replacement.

The Hardshell Reservoirs are also used with the vacuum-assisted venous return technique during cardiopulmonary bypass.

The Hardshell Reservoir each contain X-Coating, which is intended to reduce platelet adhesion on the surfaces of the device.

The CAPIOX RX® Hardshell Reservoir and the predicate SX Reservoir may be used in procedures lasting up to 6 hours.

Principles of Operation and Technology: The RX Reservoir and the predicate SX Reservoirs each utilize gravity and/or vacuum to draw blood into the device, and each has filters and defoamers that facilitate the removal of particulate and air, respectively.

Design and Materials: The design and the materials of the RX Reservoir and the SX Reservoir is essentially the same. The generic materials used in the two devices are comparable.

Performance: Comparisons of the performance of the RX Reservoir and the predicate SX Reservoirs were conducted. The comparisons demonstrated that there were no clinically significant performance differences between the devices.

Substantial Equivalence Summary:
In summary, the RX Reservoir and the predicate SX Reservoir are substantially equivalent in intended use, principles of operation and technology, design and materials, and performance. Any noted differences between the devices do not raise new issues of safety and effectiveness.

Additional Safety Information:

- Sterilization conditions have been validated in accordance with AAMI guidelines to provide a Sterility Assurance Level (SAL) of 10^{-6}.
- Ethylene Oxide residues will not exceed the maximum residue limits proposed for Part 821 of Title 21 in the Federal Register of June 23, 1978 (or as finalized or amended).
- Biocompatibility studies were conducted as recommended in the FDA General Program Memorandum #G95-1 (5/1/95): Use of International Standard ISO 10993, "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing." [External Communicating Devices, Circulating Blood, Limited Exposure (≤ 24 hours) Contact Duration]. The blood contacting materials were found to be biocompatible.
- The polymer coating material that is applied to the blood-contacting surfaces of the device was also evaluated in an *in-vivo* animal study. No adverse conditions were noted.

Conclusion:

In summary, the CAPIOX® RX Hardshell Reservoir is substantially equivalent in intended use, principles of operation and technology, design and materials, and performance to the predicate SX Hardshell Reservoir (K002238).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 5 2001

Mr. Garry A. Courtney
Regulatory Affairs
Terumo Cardiovascular Systems Corporation
125 Blue Ball Road
Elkton, MD 21921

Re: K013526
Trade Name: CAPIOX® RX Hardshell Reservior
Regulation Number: 21 CFR 870.4400
Regulation Name: Cardiopulmonary bypass blood reservoir
Regulatory Class: Class II (two)
Product Code: DTN
Dated: October 22, 2001
Received: October 23, 2001

Dear Mr. Courtney:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

NOV 1 5 2001

510(k) Number (if known): K013526

Device Name: **CAPIOX® RX Hardshell Reservoir**

Indications For Use:

The CAPIOX® RX Hardshell Reservoir is a hardshell reservoir used to store blood during extracorporeal circulation from both the venous line and the cardiotomy line. The reservoir contains filters to remove particulate matter and defoamers to facilitate air bubble removal.

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The device may be used for procedures lasting up to 6 hours.

Garry J. Courtney 10/19/01

Garry A. Courtney
Regulatory Affairs
Terumo Cardiovascular Systems

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K013526

Prescription Use _____ OR Over-The-Counter Use _____

(Per 21 CFR 801.109)